

Building Bridges: A Case for Community Health Worker Provision of Misoprostol-Only Abortion in the First Trimester

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Abstract

Introduction: The consequences of unsafe abortion are devastating to women, their families, and their communities. Medication abortion presents an important alternative to harmful self-induction practices and surgical intervention under questionable circumstances. In settings where mifepristone is unavailable, the use of misoprostol alone is a safe and effective option for terminating an unwanted pregnancy. Studies have demonstrated the safety and efficacy of administration of misoprostol by community health workers (CHW) for indications such as postpartum hemorrhage and treatment of incomplete abortion.

Objectives: The current study assesses the safety and efficacy of CHW managing misoprostol-only abortion in the first trimester.

Methods: A retrospective review of clinical files of women who received abortion services in three countries in Latin America between April 2009 and December 2015 included analysis of 173 cases.

Results: In 94% of cases, the pregnancy was terminated without any further intervention. In the remaining cases, clients were referred for manual vacuum aspiration. In four cases, a complication was reported by the provider. In one, the complication was promptly resolved through referral to a higher level of care; in the remaining three, the complication was resolved directly by the provider. In 98% of cases, women reported being satisfied with the treatment they received.

Conclusion: This study demonstrates that CHW are able to provide misoprostol-only abortion services to women effectively and safely. The benefits of this model of care also extend beyond the abortion service: CHW are able to offer women a comprehensive range of quality health services, including contraceptive services, increasing access to vital healthcare in areas with few other options.

Keywords: misoprostol, latin america, medication abortion, community health workers, maternal mortality

Introduction

Background and context

Worldwide, 303,000 women die each year due to pregnancy related causes.¹ Unsafe abortion is one of the leading causes of these deaths. The estimated 22 million unsafe abortions performed each year lead to the death of 47,000 women and the disability of another 5 million.² Nearly all deaths from unsafe abortion occur in developing countries.³

In most countries, access to safe and legal abortion is restricted to specific circumstances, such as pregnancies resulting from rape or incest, or if the woman's life is in danger,⁴ and social stigma creates further barriers to care. As a result, nearly half of all abortions are unsafe, defined by the World Health Organization (WHO) as "carried out either by

persons lacking the necessary skills or in an environment that does not conform to minimal medical standards, or both."²

Medication abortion presents an important alternative to harmful self-induction practices and unsafe surgical intervention.⁵⁻¹⁰ In settings where both mifepristone and misoprostol are available, a combination is the most common preferred protocol.^{11,12} In settings where mifepristone is unavailable, including most of Latin America, the use of misoprostol alone is a safe and effective option for terminating an unwanted pregnancy.^{5,13-17}

More than 4 million unsafe abortions occur annually in Latin America.¹⁸ As the use of misoprostol has increased in this region, maternal morbidity has decreased in both incidence and severity.¹⁹⁻²⁴ Misoprostol is widely available in much of the region and a relevant option in low-resource

settings due to low cost, ease of use, stability at room temperature, and the variety of routes of administration.²⁵

Studies investigating the safety and efficacy of misoprostol-only abortion in the first trimester are limited, and there is no common consensus on the best protocol. Routes of administration include buccal, sublingual, and vaginal, and doses and dosage vary. Across the various protocols, demonstrated efficacy has ranged significantly, from under 80%^{5,11,16,26} to more than 90%.^{7,27–30} The majority of the existing studies report efficacy around 85%.^{15,17,31–34} Efficacy rates are higher with earlier gestational ages,^{17,35} more doses,^{32,35} and greater follow-up intervals.^{27,35}

Around the world, community health workers (CHW)* currently offer misoprostol for a variety of gynecological and obstetric indications, a practice endorsed by key global bodies. The WHO recommends that auxiliary nurses and nurse midwives be able to administer misoprostol to prevent and treat postpartum hemorrhage and that lay health workers be able to administer misoprostol to prevent the same.³⁶ A review of global misoprostol implementation found that programs allowing CHW to distribute misoprostol had the greatest coverage, suggesting that leveraging providers with comparatively low skill levels can increase crucial access to the life-saving drug.³⁷ Studies have clearly demonstrated the safety and efficacy of administration of misoprostol by CHW for indications such as postpartum hemorrhage^{37–39} and treatment of incomplete abortion.⁴⁰ Further advantages include relative ease of provider training, supply chain management, and adherence to protocol.

Since 2003, the WHO has recommended that abortion be provided at the lowest appropriate level of the healthcare system.² In many communities, this comprises CHW like auxiliary nurses and traditional midwives. Research has also shown that medication abortion provided by nonphysician clinicians and mid-level providers, including ayurvedic physicians, physician's assistants, nurses, auxiliary nurse midwives, and others, is as safe and effective as procedures provided by medical doctors.^{41–44} Many investigators have called for expanding the scope of practice to include such providers to increase access to safe abortion and postabortion care.^{40,42–44}

The WHO now recommends that mid-level providers, including midwives, nurses, auxiliary nurses, and auxiliary nurse midwives, offer first trimester medication abortion. They further recommend that when women have access to accurate information and a healthcare provider if they need or want additional support, they can independently manage mifepristone and misoprostol for pregnancy termination.⁴⁵

Self-administration of misoprostol outside of the clinic offers the possibility of a private and safe way to end an unwanted pregnancy and allows the woman to have a partner, family member, or friend to support her through the process if she chooses.⁴⁶ Studies have demonstrated that this practice is safe and effective and that women are satisfied with home use.^{18,22,34,47–50} A systematic review of 4,522 cases across seven countries from 1997 to 2008 revealed no difference in

completion rate based on whether misoprostol was taken at home or at a clinic.⁴⁸

Studies have shown that CHW are capable of providing misoprostol safely for a variety of indications, and leading global health organizations recommend that they do so. The WHO recommends that more research be conducted to assess lay health workers' ability to provide first trimester medication abortion in a safe and effective manner.⁴⁵ The current study aims to fill this gap by establishing the safety and efficacy of CHW managing misoprostol-only abortion in the first trimester.

Materials and Methods

Data collection and instruments

Investigators conducted a retrospective review of clinical files of women who received abortion services from 16 CHW in three countries in Latin America between April 2009 and December 2015. CHW were identified by local organizations that provide sexual and reproductive health services.

In all three countries, abortion is legally permissible for specific indications, such as to preserve the life or health of the woman or in cases of rape or incest, and postabortion care is legal and widely available. No legal challenges to CHW or women were reported.

Criteria for inclusion in the study included 10 weeks of pregnancy or less as reported by CHW and the application of a specific protocol: three doses of 800 mcg of misoprostol administered buccally 12 hours apart, with the option of a fourth dose at a follow-up visit. Investigators reviewed all cases for which participating providers had a clinical file, and a total of 186 cases were selected for inclusion in the study. Chesapeake IRB, an independent institutional review board, determined that the research project was exempt from IRB oversight.

Researchers collected from clinical files the following data points: demographic data, including age, urban/rural dwelling, relationship status, educational level, and ethnicity; obstetric history, including gravidity, parity, and past abortions; and current treatment information, including the date of the woman's last menstrual period (LMP), weeks of pregnancy, method of calculating weeks of pregnancy, location where each dose of misoprostol was taken, follow-up, outcome of procedure, women's self-report of satisfaction, and notes on complications and referrals for further care.

Researchers established the following outcome variables for analysis:

Efficacy was defined by the percentage of misoprostol-only abortions that were completed without requiring surgical intervention. Completion was determined by the provider at follow-up.

Safety was determined by frequency of complications (e.g., hemorrhage, infection, incomplete abortion) and CHW ability to manage complications and side effects. Management of complications and side effects was considered effective if the provider either resolved the issue without further intervention or identified the issue and referred the client for appropriate higher level care.

Quality was indicated by reported follow-up with the provider, provision of a contraceptive method, and women's self-report of satisfaction with the procedure.

* In this article, this term will be used to encompass all community-based healthcare workers, including but not limited to those with an official "community health worker" designation that exists in some regions. Here, the term comprises the WHO categories of lay health workers, auxiliary nurses, auxiliary nurse midwives, nurses, and midwives.

Analysis

Data collected from clinical files were entered into a Google Sheets database by Planned Parenthood Global staff and converted to SPSS for analysis. Analysis was conducted in SPSS. Descriptive statistics were calculated for continuous variables (age; previous pregnancies, births, and abortions; and weeks of pregnancy calculated based on LMP). Frequencies were run for all categorical variables (including the remaining demographic and clinical data points). Open-ended responses (regarding any complications) were reviewed and summarized. Bivariate analyses, including independent samples *t*-tests, chi-squared tests, and Fisher’s exact tests, were utilized to assess differences between clients who required further intervention and those who did not, with regards to reproductive history, demographics, and weeks of pregnancy calculated based on LMP.

Results

Clinical protocol

Providers used the reported LMP to calculate weeks of pregnancy 82% of the time, bimanual examination 15% of the time, and ultrasound 3% of the time. Clinical histories indicated pregnancies ranging from 4.00 to 10.60 weeks (\bar{x} =8.11, SD =1.27). When investigators utilized reported LMP to calculate weeks of pregnancy, the range was between 0 and 12.43 weeks (\bar{x} =7.94, SD =1.82). In the majority (84.6%) of cases, the pregnancy dating on the clinical history was within 1 week of that calculated by investigators, with the largest discrepancy being 4.43 weeks. Based on these calculations, investigators excluded from analysis 13 cases in which the calculated number of weeks of pregnancy exceeded 10.

We included in this analysis 173 cases with an LMP of 10 weeks or less where women were provided three doses of 800 mcg of misoprostol to be administered buccally 12 hours apart, with the option of a fourth dose at the follow-up visit. The first dose of misoprostol was taken at home 55.3% of the time. This proportion increased by dose: the second dose was taken at home 86.7% of the time and the third, 86.8% of the time. In the two cases in which the woman took a fourth dose, both were taken at home.

All CHW had established referral networks, including a trusted, higher-level healthcare provider, to whom they referred clients in need of additional intervention for treatment of incomplete abortion and any additional symptoms.

Characteristics of women receiving treatment

The majority of women receiving treatment were rural dwelling, single, and with low levels of education. A detailed look at demographic data is included in Table 1. Women receiving treatment reported an average of 2.75 previous pregnancies (SD =2.323), 1.91 births (SD =2.178), and 0.29 abortions (SD =0.515). More detail is available in Table 2.

Efficacy

In 163 cases (94.2%), the pregnancy was terminated without any further intervention. CHW utilized physical examinations and women’s report of defined symptoms of abortion to confirm termination.

In the remaining cases, clients were referred for manual vacuum aspiration (MVA). In 3 of these 10 cases, the referral

TABLE 1. DEMOGRAPHIC INFORMATION

	N	%
Country of origin		
Country 1	55	31.8
Country 2	103	59.5
Country 3	15	8.7
Rural/urban dwelling		
Rural	139	82.2
Urban	30	17.8
Relationship status		
Married/living with partner	64	37.9
Separated/divorced/widowed	3	1.8
Single	102	60.4
Education		
None	30	17.6
Primary schooling	80	47.1
Secondary schooling	47	27.6
Beyond secondary	13	7.6
Ethnicity		
African descent	29	23.8
Indigenous	46	37.7
Mestiza	45	36.9
Other	2	1.9
Age		
Minimum	15	
Maximum	42	
Mean (SD)	25.09 (6.58)	

was for continuing pregnancy and in four, for ongoing bleeding and continuing pregnancy. In the remaining three, clinical records indicate referral for MVA but not the specific cause.

There were no statistically significant differences between clients who required further intervention and those who did not, with regards to reproductive history (gravidity, parity, number of previous abortions), demographics (ethnicity, age, relationship status, urban/rural dwelling, level of education), or weeks of pregnancy calculated based on LMP.

Safety

In four cases (2.3%), a complication was reported by the provider. One case of heavy bleeding required a higher level of care and was resolved through referral, a blood transfusion, and MVA. One case of moderate bleeding was resolved directly by the provider through IV fluids and antibiotics. One case of moderate bleeding was observed by the CHW and resolved without further intervention or referral. Finally, one

TABLE 2. PREGNANCY HISTORY

	N	%
Previous pregnancies		
0	19	11.4
1–3	96	57.5
4–6	43	25.7
7+	9	5.4
Previous abortions		
0	124	74.3
1	38	22.8
2	5	3.0

TABLE 3. SIDE EFFECTS

	N	%
Chills	128	75.3
Cramping	165	95.4
Diarrhea	61	35.9
Fever	82	49.1
Headache	77	46.7
Nausea	95	55.6
Vomiting	32	18.7

case of excessive vomiting was observed and resolved without further intervention.

The most common side effects included cramping and chills. Reported side effects are included in Table 3.

Quality

Ninety two percent of women returned for their follow-up visit, and providers spoke with the remaining 8.0% to confirm success of treatment, either by phone or in person.

As part of their postprocedure counseling, 70.6% of women chose a contraceptive method. The most common method elected was injectable contraceptives (45.5%), followed by oral contraceptives (40.9%), condoms (5.7%), implants (4.6%), intrauterine device (1.1%), and tubal ligation (1.1%). The CHW provided the injectable and oral contraceptives and condoms themselves and referred women to a higher level of care for the long-acting and permanent methods.

Of the total sample, 98.2% of women reported being satisfied with the treatment they received.

Discussion

Barriers to abortion care range from legal and regulatory (including legal restrictions and lack of appropriate regulation) to social (including pervasive stigma and lack of knowledge of rights) to structural (including lack of training and support and of supplies). These barriers do not decrease the incidence of abortion, but do increase the risk of death and disability from abortion because they lead to fewer trained medical professionals, fewer facilities offering safe abortion services and postabortion care, less knowledge about where to go for these services, higher costs, and more social stigma.⁵¹

This study suggests that CHW are able to provide misoprostol-only abortion services to women effectively and safely. At 94.2%, the efficacy of the current protocol was higher than reported from many studies of misoprostol-only abortion in the first trimester. We attribute this to several factors.

Consistent with previous research, we believe that the greater number of doses (three or four) and confining our study to cases with an LMP of 10 weeks or fewer influenced the high efficacy rate. In addition, by providing culturally appropriate information, counseling, and care at the community level, CHW are able to offer ongoing support during the medication abortion process. Each of the CHW is a member of both their community and the health sector, with strong links to both women in need of services and providers who can offer more advanced care as needed. We postulate that this support increases women's confidence in the procedure and prompts them to wait enough time for the medication to work, which is also consistent with previous

research linking longer follow-up intervals to greater efficacy. Similarly, the fact that many of the women were rural dwelling and with few alternative options for pregnancy termination may also have caused them to wait longer to seek further intervention.

Side effects were consistent with those reported in other research on misoprostol use. However, a limitation of the study is the fact that information about side effects was not systematically collected in a research protocol; investigators reported the side effects as noted in clinical histories, but were unable to confirm in all cases whether they were recorded due to women's self-report or clinician observation.

Few complications arose. While some required a higher level of care than what CHW were able to offer, providers in the current study demonstrated the ability to consult higher level providers and refer as necessary. In these cases, CHW acted as a bridge to more advanced obstetric and gynecological care, as well as access to a more formal healthcare system.

In the majority of cases, the pregnancy dating on the clinical history was accurate. The few discrepancies between dating as reported by CHW and as calculated by investigators indicated that CHW may need additional training on accurate pregnancy dating and maintenance of clinical files. However, given the flexible timing of the misoprostol regimen, potential miscalculations did not appear to affect the efficacy or safety of the procedure.

The benefits of this model of care extend beyond the one-time abortion service. CHW are able to offer women a comprehensive range of quality health services, increasing access to vital healthcare in areas with few other options. In addition, with the high proportion of women who received a contraceptive method following the procedure, CHW offering abortion services provide an opportunity for women who might not have otherwise done so to receive contraceptive counseling and services. These additional services, especially contraceptive use, are key factors in improving women's health.

Conclusions

Access to abortion is an issue of both public health and human rights. According to the WHO, "abortion laws and services should protect the health and human rights of all women, including adolescents. They should not create situations that lead women and adolescents to seek unsafe abortion."²

Expanding health system recommendations to include misoprostol-only abortion services offered by CHW provides an opportunity to expand access to safe abortion. The results of this study can be utilized to inform clinical practice regarding the provision of abortion services by CHW, as well as advocacy around access to safe abortion, ultimately expanding access to safe abortion services in low-resource settings.

CHW in this study were able to assess and date pregnancy, follow appropriate protocols for the administration of misoprostol, and recognize, manage, and refer for gynecological complications. The infrastructure needed to support CHW is limited. An established referral system for obstetrical emergencies, including an emergency transportation plan and a reliable supply chain of essential medications, including contraceptive methods and misoprostol, is crucial.

The WHO also states that “the availability of facilities and trained providers within reach of the entire population is essential to ensuring access to safe abortion services.”² The implementation of medication abortion services by CHW has the potential to reduce the impact of unsafe abortion, particularly in developing countries. An integrated strategy would include increasing access to education about sexual and reproductive health and rights and integrated reproductive health services.

The provision of medication abortion services by CHW can be safe and effective. Expanding the scope of duties that CHW are able to perform and empowering CHW to offer safe abortion services can help overcome barriers to care.

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Disclaimer

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Author Disclosure Statement

No competing financial interests exist.

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